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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/775,235	02/11/2004	Arthur E. Uber III	071419-0308016	1007

21140 7590 01/29/2007
GREGORY L BRADLEY
MEDRAD INC
ONE MEDRAD DRIVE
INDIANOLA, PA 15051

EXAMINER

SMITH, RUTH S

ART UNIT PAPER NUMBER

3737

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	01/29/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No. 10/775,235	Applicant(s) UBER ET AL.	
	Examiner Ruth S. Smith	Art Unit 3737	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 03 November 2006.
 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 22-30,32-35,38 and 41-57 is/are pending in the application.
 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
 5) ☐ Claim(s) _____ is/are allowed.
 6) ☒ Claim(s) 22-30,32-35,38 and 41-57 is/are rejected.
 7) ☐ Claim(s) _____ is/are objected to.
 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 a) ☐ All b) ☐ Some * c) ☐ None of:
 1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date: _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date: _____ | 6) <input type="checkbox"/> Other: _____ |

Specification

The disclosure is objected to because of the following informalities: On page 1, applicant should update the status of the continuing data. Appropriate correction is required.

The amendment filed June 13, 2005 is objected to under 35 U.S.C. 132(a) because it introduces new matter into the disclosure. 35 U.S.C. 132(a) states that no amendment shall introduce new matter into the disclosure of the invention. The added material which is not supported by the original disclosure is as follows: the control unit actuates the first and second pressurizing devices at substantially the same time to deliver the first and second fluid media to a balloon. Applicant is required to cancel the new matter in the reply to this Office Action.

Claim Rejections - 35 USC § 112

Claims 50-51 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The specification, as originally filed, fails to disclose that the control unit actuates the first and second pressurizing devices at substantially the same time to deliver the first and second fluid media to a balloon.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein

were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 22-28,30,32-35,38,41-57 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kampfe et al in view of Millar (4,901,731). Kampfe et al disclose a fluid delivery system used to provide varying amounts of contrast media and a diluent which are mixed together and provided to a patient during a diagnostic procedure. The delivery pipe can be connected to a **variety of different types of receiving containers depending upon the procedure being performed**. The fluid delivery system includes a source of a contrast medium 12, a source of a diluent 14, first and second pressuring devices 26,28, which can comprise a peristaltic pump, and a fluid path 16,18, 19, 22,24. The fluid path also includes valves 56,62,66 a tube such as formed by element 22 and a per-patient connect provided by valve 66 and end of tube 24. Kampfe et al disclose that instead of the two paths 16,18 joining to form path 19, two separate paths can enter the mixing chamber 20. Kampfe et al disclose that the media from source 12 first fills chamber 20 followed by the diluent from source 14. It would have been obvious to one skilled in the art to have modified Kampfe et al such that the chamber is filled simultaneously with the fluids from both sources given the use of separate paths from the sources in order to reduce the overall fill time. The system further includes an input device in communication with the control unit. The use of an input device such as a mouse or keyboard, which can be hand-held, is a well known expedient in the art. It is well known in an angioplasty procedure to fill the balloon on an angioplasty catheter with the contrast media. An example of such is seen in Millar. It would have been obvious to one skilled in the art to have modified Kampfe et al such that the contrast media is directed to fill a balloon on an angioplasty catheter. Such a modification allows the contrast media to be used for a procedure that requires the use of a contrast media in order for it to be properly carried out. With respect to claims 46-49, the fluid is delivered under pressure and the manner in which the pressure is provided would have

been an obvious design choice in the absence of any showing of unexpected results. With respect to claims 55-56, the use of valve 66 will allow the per-patient portion to be disconnected from the fluid path.

Claim 29 is rejected under 35 U.S.C. 103(a) as being unpatentable over Kampfe et al in view of Millar as applied to claim 22 above, and further in view of Heilman et al (5,569,181) or Ross et al (5,433,704). Heilman et al and Ross et al each disclose the use of an air detector in a fluid delivery system in order to prevent air bubbles from being delivered to the patient. It would have been obvious to one skilled in the art to have further modified Kampfe et al such that it includes an air detector. The advantage of such is to prevent the introduction of air bubbles into the system because they can cause harm to the patient.

Response to Arguments

Applicant's arguments filed November 3, 2006 have been fully considered but they are not persuasive. With respect to the new matter rejection, the portions of the original disclosure cited by the applicant fail to provide support for the recitation of actuating the first and second pressurizing devices at substantially the same time. With regard to the rejection of claims under 35 USC 103, while Kampfe et al gives some examples of what type of container is filled with the contrast medium, Kampfe et al does not preclude the filling of a balloon catheter. One skilled in the art would have recognized that it would have been obvious to use Kampfe et al to fill any type of container that is known to be filled with a contrast media depending upon the procedure being performed. Millar is used as a teaching that it is known to fill an inflating balloon under pressure using a contrast media and diluent. Therefore, the examiner maintains the rejection of all claims in view of the combined teachings of Kampfe et al and Millar.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP

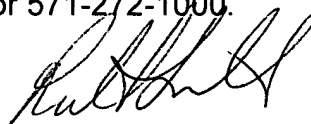
§ 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ruth S. Smith whose telephone number is 571-272-4745. The examiner can normally be reached on M-F 7:30 AM-4:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brian Casler can be reached on 571-272-4956. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



Ruth S. Smith
Primary Examiner
Art Unit 3737